TITLE I

CERTIFICATION OF AGENTS AND UTILIZATION REVIEW PROCESS

§ 4900. Definitions.

For purposes of this article:

1. "Adverse determination" means a determination by a utilization review agent that an admission, extension of stay, or other health care service, upon review based on the information provided, is not medically necessary.

2. "Clinical peer reviewer" means:

(a) for purposes of title one of this article:

(i) a physician who possesses a current and valid non-restricted license to practice medicine; or

(ii) a health care professional other than a licensed physician who:

(A) where applicable, possesses a current and valid non-restricted license, certificate or registration or, where no provision for a license, certificate or registration exists, is credentialed by the national accrediting body appropriate to the profession; and

(B) is in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under review; and

(b) for purposes of title two of this article:

(i) a physician who:

(A) possesses a current and valid non-restricted license to practice medicine;

(B) where applicable, is board certified or board eligible in the same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under appeal;

(C) has been practicing in such area of specialty for a period of at least five years; and

(D) is knowledgeable about the health care service or treatment under appeal; or

(ii) a health care professional other than a licensed physician who:

(A) where applicable, possesses a current and valid non-restricted license, certificate or registration;

(B) where applicable, is credentialed by the national accrediting body appropriate to the profession in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under appeal;

(C) has been practicing in such area of specialty for a period of at least five years;

(D) is knowledgeable about the health care service or treatment under appeal; and

(E) where applicable to such health care professional's scope of practice, is clinically supported by a physician who possesses a current and valid non-restricted license to practice medicine.

(c) Nothing herein shall be construed to change any statutorily-defined scope of practice.

2-a. "Clinical standards" means those guidelines and standards set forth in the utilization review plan by the utilization review agent whose adverse determination is under appeal.

2-b. "Clinical trial" means a peer-reviewed study plan which has been

(a) reviewed and approved by a qualified institutional review board, and

(b) approved by one of the National Institutes of Health (NIH), or an NIH cooperative group or an NIH center, or the Food and Drug Administration in the form of an investigational new drug exemption, or the federal Department of Veteran Affairs, or a qualified nongovernmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants, or an institutional review board of a facility which has a

multiple project assurance approved by the Office of Protection from Research Risks of the National Institutes of Health. As used in this subdivision, the term "cooperative groups" means formal networks of facilities that collaborate on research projects and have established NIH-approved peer review programs operating within their groups; and that include, but are not limited to, the National Cancer Institute (NCI) Clinical Cooperative Groups, the NCI Community Clinical Oncology Program (CCOP), the AIDS Clinical Trials Groups (ACTG), and the Community Programs for Clinical Research in AIDS (CPCRA).

2-c. "Disabling condition or disease" means a condition or disease which, according to the current diagnosis of the enrollee's attending physician, is consistent with the definition of "disabled person" pursuant to subdivision five of section two hundred eight of the social services law.

3. "Emergency condition" means a medical or behavioral condition, the onset of which is sudden, that manifests itself by symptoms of sufficient severity, including severe pain, that a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in

(a) placing the health of the person afflicted with such condition in serious jeopardy, or in the case of a behavioral condition placing the health of such person or others in serious jeopardy;

(b) serious impairment to such person's bodily functions;

(c) serious dysfunction of any bodily organ or part of such person; or

(d) serious disfigurement of such person.

4. "Enrollee" means a person subject to utilization review.

4-a. "Experimental and investigational treatment review plan" means:

(a) a description of the process for developing the written clinical review criteria used in rendering an experimental and investigational treatment review determination; and

(b) a description of the qualifications and experience of the clinical peers who developed the criteria, who are responsible for periodic evaluation of the criteria, and who use the written clinical review criteria in the process of reviewing proposed experimental and investigational health services and procedures.

4-b. "External appeal" means an appeal conducted by an external appeal agent in accordance with the provisions of section forty-nine hundred fourteen of this article.

4-c. "External appeal agent" means an entity certified by the commissioner pursuant to section forty-nine hundred eleven of this article.

4-d. "Final adverse determination" means an adverse determination which has been upheld by a utilization review agent with respect to a proposed health care service following a standard appeal, or an expedited appeal where applicable, pursuant to section forty-nine hundred four of this title.

4-e. "Health care plan" means any organization certified under article forty-four of this chapter.

5. (a) For purposes of this title and for appeals requested pursuant to paragraph (a) of subdivision two of section forty-nine hundred ten of title two of this article, "health care service" means:

(i) health care procedures, treatments or services

(A) provided by a facility licensed pursuant to article twenty-eight, thirty-six, forty-four or forty-seven of this chapter or pursuant to article nineteen, twenty-three or thirty-one of the mental hygiene law; or

(B) provided by a health care professional; and

(ii) the provision of pharmaceutical products or services or durable medical equipment.

(b) For purposes of appeals requested pursuant to paragraph (b) of subdivision two of section forty-nine hundred ten of title two of this article, "health care services" shall mean experimental or investigational procedures, treatments or services, including:

(A) services provided within a clinical trial, and

(B) the provision of a pharmaceutical product pursuant to prescription by the enrollee's attending physician for a use other than those uses for which such pharmaceutical product has been approved for marketing by the federal Food and Drug Administration; to the extent that coverage for such services are prohibited by law from being excluded under the plan. Provided that nothing in this subdivision shall be construed to define what are covered services pursuant to a subscriber contract or governmental health benefit program.

6. "Health care professional" means an appropriately licensed, registered or certified health care professional pursuant to title eight of the education law or a health care professional comparably licensed, registered or certified by another state.

7. "Health care provider" means a health care professional or a facility licensed pursuant to articles twenty-eight, thirty-six, forty-four or forty-seven of this chapter or a facility licensed pursuant to article nineteen, twenty-three or thirty-one of the mental hygiene law.

7-a. "Life-threatening condition or disease" means a condition or disease which, according to the current diagnosis of the enrollee's attending physician, has a high probability of causing the enrollee's death.

7-b. "Material familial affiliation" means any relationship as a spouse, child, parent, sibling, spouse's parent, spouse's child, child's parent, child's spouse, or sibling's spouse.

7-c. "Material financial affiliation" means any financial interest of more than five percent of total annual revenue or total annual income of an external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal. The term "material financial affiliation" shall not include revenue received from a health care plan by

(a) an external appeal agent to conduct an external appeal pursuant to section forty-nine hundred fourteen of title two of this article, or

(b) a clinical peer reviewer for health services rendered to enrollees.

7-d. "Material professional affiliation" means any physician-patient relationship, any partnership or employment relationship, a shareholder or similar ownership interest in a professional corporation, or any independent contractor arrangement that constitutes a material financial affiliation with any expert or any officer or director of the independent organization.

7-e. "Medical and scientific evidence" means the following sources:

(a) peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(b) peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta

Medicus, Medline and MEDLARS database Health Services Technology Assessment Research;

(c) peer-reviewed abstracts accepted for presentation at major medical association meetings;

(d) peer-reviewed literature shall not include publications or supplements to publications sponsored to a significant extent by a pharmaceutical manufacturing company or medical device manufacturer;

(e) medical journals recognized by the secretary of Health and Human Services, under section 1861 (t)(2) of the federal Social Security Act;

(f) the following standard reference compendia:

(i) the American Hospital Formulary Service - Drug Information;

(ii) the American Medical Association Drug Evaluation;

(iii) the American Dental Association Accepted Dental Therapeutics;and

(iv) the United States Pharmacopeia - Drug Information;

(g) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the federal Agency for Health Care Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Health Care Financing Administration, Congressional Office of Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.

8. "Utilization review" means the review to determine whether health care services that have been provided, are being provided or are proposed to be provided to a patient, whether undertaken prior to, concurrent with or subsequent to the delivery of such services are medically necessary. For the purposes of this article none of the following shall be considered utilization review:

(a) Denials based on failure to obtain health care services from a designated or approved health care provider as required under a subscriber's contract;

(b) Where any determination is rendered pursuant to subdivision three-a of section twenty-eight hundred seven-c of this chapter;

(c) The review of the appropriateness of the application of a particular coding to a patient, including the assignment of diagnosis and procedure;

(d) Any issues relating to the determination of the amount or extent of payment other than determinations to deny payment based on an adverse determination; and

(e) Any determination of any coverage issues other than whether health care services are or were medically necessary.

9. "Utilization review agent" means any company, organization or other entity performing utilization review, except:

(a) an agency of the federal government;

(b) an agent acting on behalf of the federal government, but only to the extent that the agent is providing services to the federal government;

(c) an agent acting on behalf of the state and local government for services provided pursuant to title XIX of the federal social security act;

(d) a hospital's internal quality assurance program except if associated with a health care financing mechanism; or

(e) any insurer subject to article thirty-two or forty-three of the insurance law and any independent utilization review agent performing utilization review under a contract with such insurer, which shall be subject to article forty-nine of the insurance law.

10. "Utilization review plan" means:

(a) a description of the process for developing the written clinical review criteria;

(b) a description of the types of written clinical information which the plan might consider in its clinical review, including but not limited to, a set of specific written clinical review criteria;

(c) a description of practice guidelines and standards used by a utilization review agent in carrying out a determination of medical necessity;

(d) the procedures for scheduled review and evaluation of the written clinical review criteria; and

(e) a description of the qualifications and experience of the health care professionals who developed the criteria, who are responsible for periodic evaluation of the criteria and of the health care professionals or others who use the written clinical review criteria in the process of utilization review.

§ 4901. Registration of utilization review agents.

1. Every utilization review agent who conducts the practice of utilization review shall biennially register with the commissioner and report, in a statement subscribed and affirmed as true under the penalties of perjury, the information required pursuant to subdivision two of this section.

2. Such report shall contain a description of the following:

(a) The utilization review plan;

(b) Those circumstances, if any, under which utilization review may be delegated to a utilization review program conducted by a facility licensed pursuant to article twenty-eight of this chapter or pursuant to article thirty-one of the mental hygiene law;

* (c) The provisions by which an enrollee, the enrollee's designee, or a health care provider may seek reconsideration of, or appeal from, adverse determinations by the utilization review agent, in accordance with the provisions of this title, including provisions to ensure a timely appeal and that an enrollee, the enrollee's designee, and, in the case of an adverse determination involving a retrospective determination, the enrollee's health care provider, is informed of their right to appeal adverse determinations;
* Effective 99/07/01

* (d) Procedures by which a decision on a request for utilization review for services requiring preauthorization shall comply with timeframes established pursuant to this title;
* NB Effective 99/07/01

(e) A description of an emergency care policy, which shall include the procedures under which an emergency admission shall be made or emergency treatment shall be given;

(f) A description of the personnel utilized to conduct utilization review including a description of the circumstances under which utilization review may be conducted by:

(i) administrative personnel,

(ii) health care professionals who are not clinical peer reviewers, and

(iii) clinical peer reviewers;

(g) A description of the mechanisms employed to assure that administrative personnel are trained in the principles and procedures of intake screening and data collection and are appropriately monitored by a licensed health care professional while performing an administrative review;

(h) A description of the mechanisms employed to assure that health care professionals conducting utilization review are:

(i) appropriately licensed, registered or certified; and

(ii) trained in the principles, procedures and standards of such utilization review agent;

(i) A description of the mechanisms employed to assure that only a clinical peer reviewer shall render an adverse determination;

(j) Provisions to ensure that appropriate personnel of the utilization review agent are reasonably accessible by toll-free telephone:

(i) not less than forty hours per week during normal business hours, to discuss patient care and allow response to telephone requests, and to ensure that such utilization review agent has a telephone system capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours and to ensure response to accepted or recorded messages not later than the next business day after the date on which the call was received; or

* (ii) notwithstanding the provisions of subparagraph (i) of this paragraph, not less than forty hours per week during normal business hours, to discuss patient care and allow response to telephone requests, and to ensure that, in the case of a request submitted pursuant to subdivision three of section forty-nine hundred three of this title or an expedited appeal filed pursuant to subdivision two of section forty- nine hundred four of this title, on a twenty-four hour a day, seven day a week basis;
* NB Effective 99/07/01

(k) The policies and procedures to ensure that all applicable state and federal laws to protect the confidentiality of individual medical and treatment records are followed;

* (l) A copy of the materials to be disclosed to an enrollee or prospective enrollee pursuant to this title and section forty-four hundred eight of this chapter;
* NB Effective 99/07/01

* (m) A description of the mechanisms employed by the utilization review agent to assure that all contractors, subcontractors, subvendors, agents and employees affiliated by contract or otherwise with such utilization review agent will adhere to the standards and requirements of this title; and
* NB Effective 99/07/01

(n) A list of the payors for which the utilization review agent is performing utilization review in this state.

3. Upon receipt of the report, the commissioner shall issue an acknowledgment of the filing.

* 4. A registration issued under this title shall be valid for a period of not more than two years, and may be renewed for additional periods of not more than two years each.
NB Effective 99/07/01

5. A health maintenance organization licensed pursuant to article forty-three of the insurance law or certified under article forty-four of this chapter shall not be required to register as a utilization review agent, provided that such health maintenance organization has otherwise provided the information required pursuant to subdivision two of this section to the commissioner.

6. The clinical review criteria and standards contained within the utilization review plan and the list of payors required pursuant to paragraph (n) of subdivision two of this section shall not be subject to disclosure pursuant to the provisions of article six of the public officers law.

§ 4902. Utilization review program standards.

1. * Each utilization review agent shall adhere to utilization review program standards consistent with the provisions of this title which shall, at a minimum, include:
* NB Effective 99/07/01

(a) Appointment of a medical director, who is a licensed physician; provided, however, that the utilization review agent may appoint a clinical director when the utilization review performed is for a discrete category of health care service and provided further that the clinical director is a licensed health care professional who typically manages the category of service. Responsibilities of the medical director, or, where appropriate, the clinical director, shall include, but not be limited to, the supervision and oversight of the utilization review process;

* (b) Development of written policies and procedures that govern all aspects of the utilization review process and a requirement that a utilization review agent shall maintain and

make available to enrollees and health care providers a written description of such procedures including procedures to appeal an adverse determination together with a description, jointly promulgated by the commissioner and the superintendent of insurance as required pursuant to subdivision five of section forty-nine hundred fourteen of this article, of the external appeal process established pursuant to title two of this article and the time frames for such appeals;
* NB Effective 99/07/01

(c) Utilization of written clinical review criteria developed pursuant to a utilization review plan;

(d) Establishment of a process for rendering utilization review determinations which shall, at a minimum, include: written procedures to assure that utilization reviews and determinations are conducted within the timeframes established herein; procedures to notify an enrollee, an enrollee's designee and/or an enrollee's health care provider of adverse determinations; and procedures for appeal of adverse determinations including the establishment of an expedited appeals process for denials of continued inpatient care or where there is imminent or serious threat to the health of the enrollee;

(e) Establishment of a written procedure to assure that the notice of an adverse determination includes:

(i) the reasons for the determination including the clinical rationale, if any;

* (ii) instructions on how to initiate standard and expedited appeals pursuant to section forty-nine hundred four and an external appeal pursuant to section forty-nine hundred fourteen of this article; and
* NB Effective 99/07/01

(iii) notice of the availability, upon request of the enrollee or the enrollee's designee, of the clinical review criteria relied upon to make such determination;

(f) Establishment of a requirement that appropriate personnel of the utilization review agent are reasonably accessible by toll-free telephone:

(i) not less than forty hours per week during normal business hours to discuss patient care and allow response to telephone requests, and to ensure that such utilization review agent has a telephone system capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours and to ensure response to accepted or recorded messages not less than one business day after the date on which the call was received; or

* (ii) notwithstanding the provisions of subparagraph (i) of this paragraph, not less than forty hours per week during normal business hours, to discuss patient care

and allow response to telephone requests, and to ensure that, in the case of a request submitted pursuant to subdivision three of section forty-nine hundred three of this title or an expedited appeal filed pursuant to subdivision two of section forty- nine hundred four of this title, on a twenty-four hour a day, seven day a week basis;

* NB Effective 99/07/01

(g) Establishment of appropriate policies and procedures to ensure that all applicable state and federal laws to protect the confidentiality of individual medical records are followed;

(h) Establishment of a requirement that emergency services rendered to an enrollee shall not be subject to prior authorization nor shall reimbursement for such services be denied on retrospective review; provided, however, that such services are medically necessary to stabilize or treat an emergency condition.

2. Each utilization review agent shall assure adherence to the requirements stated in subdivision one of this section by all contractors, subcontractors, subvendors, agents and employees affiliated by contract or otherwise with such utilization review agent.

§ 4903. Utilization review determinations.

1. Utilization review shall be conducted by:

(a) Administrative personnel trained in the principles and procedures of intake screening and data collection, provided, however, that administrative personnel shall only perform intake screening, data collection and non-clinical review functions and shall be supervised by a licensed health care professional;

(b) A health care professional who is appropriately trained in the principles, procedures and standards of such utilization review agent; provided, however, that a health care professional who is not a clinical peer reviewer may not render an adverse determination; and

(c) A clinical peer reviewer where the review involves an adverse determination.

2. A utilization review agent shall make a utilization review determination involving health care services which require pre-authorization and provide notice of a determination to the enrollee or enrollee's designee and the enrollee's health care provider by telephone and in writing within three business days of receipt of the necessary information.

3. A utilization review agent shall make a determination involving continued or extended health care services, or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider and provide notice of such determination to the enrollee or the enrollee's designee, which may be satisfied by notice to the enrollee's

health care provider, by telephone and in writing within one business day of receipt of the necessary information. Notification of continued or extended services shall include the number of extended services approved, the new total of approved services, the date of onset of services and the next review date.

4. A utilization review agent shall make a utilization review determination involving health care services which have been delivered within thirty days of receipt of the necessary information.

5. Notice of an adverse determination made by a utilization review agent shall be in writing and must include:

(a) the reasons for the determination including the clinical rationale, if any;

* (b) instructions on how to initiate standard and expedited appeals pursuant to section forty-nine hundred four and an external appeal pursuant to section forty-nine hundred fourteen of this article; and
* NB Effective 99/07/01

(c) notice of the availability, upon request of the enrollee, or the enrollee's designee, of the clinical review criteria relied upon to make such determination. Such notice shall also specify what, if any, additional necessary information must be provided to, or obtained by, the utilization review agent in order to render a decision on the appeal.

6. In the event that a utilization review agent renders an adverse determination without attempting to discuss such matter with the enrollee's health care provider who specifically recommended the health care service, procedure or treatment under review, such health care provider shall have the opportunity to request a reconsideration of the adverse determination. Except in cases of retrospective reviews, such reconsideration shall occur within one business day of receipt of the request and shall be conducted by the enrollee's health care provider and the clinical peer reviewer making the initial determination or a designated clinical peer reviewer if the original clinical peer reviewer cannot be available. In the event that the adverse determination is upheld after reconsideration, the utilization review agent shall provide notice as required pursuant to subdivision five of this section. Nothing in this section shall preclude the enrollee from initiating an appeal from an adverse determination.

* 7. Failure by the utilization review agent to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section forty nine hundred four of this title.
* NB Effective 99/07/01

§ 4904. Appeal of adverse determinations by utilization review agents.

1. An enrollee, the enrollee's designee and, in connection with retrospective adverse determinations, an enrollee's health care provider, may appeal an adverse determination rendered by a utilization review agent.

2. A utilization review agent shall establish an expedited appeal process for appeal of an adverse determination involving:

(a) continued or extended health care services, procedures or treatments or additional services for an enrollee undergoing a course of continued treatment prescribed by a health care provider; or

* (b) an adverse determination in which the health care provider believes an immediate appeal is warranted except any retrospective determination. Such process shall include mechanisms which facilitate resolution of the appeal including but not limited to the sharing of information from the enrollee's health care provider and the utilization review agent by telephonic means or by facsimile. The utilization review agent shall provide reasonable access to its clinical peer reviewer within one business day of receiving notice of the taking of an expedited appeal. Expedited appeals shall be determined within two business days of receipt of necessary information to conduct such appeal. Expedited appeals which do not result in a resolution satisfactory to the appealing party may be further appealed through the standard appeal process, or through the external appeal process pursuant to section forty-nine hundred fourteen of this article as applicable.
* NB Effective 99/07/01

* 3. A utilization review agent shall establish a standard appeal process which includes procedures for appeals to be filed in writing or by telephone. A utilization review agent must establish a period of no less than forty-five days after receipt of notification by the enrollee of the initial utilization review determination and receipt of all necessary information to file the appeal from said determination. The utilization review agent must provide written acknowledgment of the filing of the appeal to the appealing party within fifteen days of such filing and shall make a determination with regard to the appeal within sixty days of the receipt of necessary information to conduct the appeal. The utilization review agent shall notify the enrollee, the enrollee's designee and, where appropriate, the enrollee's health care provider, in writing, of the appeal determination within two business days of the rendering of such determination. The notice of the appeal determination shall include:

(a) the reasons for the determination; provided, however, that where the adverse determination is upheld on appeal, the notice shall include the clinical rationale for such determination; and

(b) a notice of the enrollee's right to an external appeal together with a description, jointly promulgated by the commissioner and the superintendent of insurance as required pursuant to subdivision five of section forty-nine hundred fourteen of this

article, of the external appeal process established pursuant to title two of this article and the time frames for such external appeals.
* NB Effective 99/07/01

* 4. Both expedited and standard appeals shall only be conducted by clinical peer reviewers, provided that any such appeal shall be reviewed by a clinical peer reviewer other than the clinical peer reviewer who rendered the adverse determination.
* NB Effective 99/07/01

* 5. Failure by the utilization review agent to make a determination within the applicable time periods in this section shall be deemed to be a reversal of the utilization review agent's adverse determination.
* NB Effective 99/07/01

§ 4905. Required and prohibited practices.

1. Each utilization review agent shall have written procedures for assuring that patient-specific information obtained during the process of utilization review will be:

(a) kept confidential in accordance with applicable state and federal laws; and

(b) shared only with the insured, the insured's designee, the insured's health care provider and those who are authorized by law to receive such information.

(2) Summary data shall not be considered confidential if it does not provide information to allow identification of individual patients.

(3) Any health care professional who makes determinations regarding the medical necessity of health care services during the course of utilization review shall be appropriately licensed, registered or certified.

(4) A utilization review agent shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors based on:

(a)either a percentage of the amount by which a claim is reduced for payment or the number of claims or the cost of services for which the person has denied authorization or payment; or

(b) any other method that encourages the rendering of an adverse determination.

(5) If a health care service has been specifically preauthorized or approved for an insured by a utilization review agent, a utilization review agent shall not pursuant to retrospective review revise or modify the specific standards, criteria or procedures used for the utilization review for procedures, treatment and services delivered to the insured, during the same course of treatment.

(6) Utilization review shall not be conducted more frequently than is reasonably required to assess whether the health care services under review are medically necessary.

(7) When making prospective, concurrent and retrospective determinations, utilization review agents shall collect only such information as is necessary to make such determination and shall not routinely require health care providers to numerically code diagnoses or procedures to be considered for certification or routinely request copies of medical records of all patients reviewed. During prospective or concurrent review, copies of medical records shall only be required when necessary to verify that the health care services subject to such review are medically necessary. In such cases, only the necessary or relevant sections of the medical record shall be required. A utilization review agent may request copies of partial or complete medical records retrospectively. This subsection shall not apply to health maintenance organizations licensed pursuant to article forty-three of this chapter or certified pursuant to article forty-four of the public health law.

(8) In no event shall information be obtained from the health care providers for the use of the utilization review agent by persons other than health care professionals, medical record technologists or administrative personnel who have received appropriate training.

(9) The utilization review agent shall not undertake utilization review at the site of the provision of health care services unless the utilization review agent:

(a) Identifies himself or herself by name and the name of his or her organization, including displaying photographic identification which includes the name of the utilization review agent and clearly identifies the individual as representative of the utilization review agent;

(b) Whenever possible, schedules review at least one business day in advance with the appropriate health care provider;

(c) If requested by a health care provider, assures that the on-site review staff register with the appropriate contact person, if available, prior to requesting any

clinical information or assistance from the health care provider; and

(d) Obtains consent from the insured or the insured's designee before interviewing the patient's family, or observing any health care service being provided to the insured.

(e) This subsection shall not apply to health care professionals engaged in providing care or case management or making on-site discharge decisions.

(10) A utilization review agent shall not base an adverse determination on a refusal to consent to observing any health care service.

(11) A utilization review agent shall not base an adverse determination on lack of reasonable access to a health care provider's medical or treatment records unless the utilization review agent has provided reasonable notice to the insured, the insured's designee or the insured's health care provider, in which case the insured must be notified, and has complied with all provisions of subsection nine of this section.

(12) Neither the utilization review agent nor the entity for which the agent provides utilization review shall take any action with respect to a patient or a health care provider that is intended to penalize such insured, the insured's designee, or the insured's health care provider for, or to discourage such insured, the insured's designee, or the insured's health care provider from undertaking an appeal, dispute resolution or judicial review of an adverse determination.

(13) In no event shall an insured, an insured's designee, an insured's health care provider, any other health care provider, or any other person or entity be required to inform or contact the utilization review agent prior to the provision of emergency care, including emergency treatment or emergency admission.

(14) No contract or agreement between a utilization review agent and a health care provider shall contain any clause purporting to transfer to the health care provider by indemnification or otherwise any liability relating to activities, actions or omissions of the utilization review agent as opposed to the health care provider.

(15) A health care professional providing health care services to an insured shall be prohibited from serving as the clinical peer reviewer for such insured in connection with the health care services being provided to the insured.

***§ 4906. Waiver.**

Any agreement which purports to waive, limit, disclaim, or in any way diminish the rights set forth in this article, except as provided pursuant to section four thousand nine hundred ten of this article shall be void as contrary to public policy.

*NB Effective 99/07/01

§ 4907. Rights and remedies.

The rights and remedies conferred in this article upon enrollees and health care providers shall be cumulative and in addition to and not in lieu of any other rights or remedies available under law.

§ 4908. Applicability to ERISA Plans.

Notwithstanding the foregoing, the provisions of this article shall not apply to any utilization review conducted by, or on behalf of, a self-insured employee welfare benefit plan, as defined in the employee retirement income security act of 1974, as amended.

TITLE II
RIGHT TO EXTERNAL APPEAL

***§ 4910. Right to external appeal established.**

1. There is hereby established an enrollee's right to an external appeal of a final adverse determination by a health care plan.

2. An enrollee, the enrollee's designee and, in connection with retrospective adverse determinations, an enrollee's health care provider, shall have the right to request an external appeal when:

(a) (i) the enrollee has had coverage of a health care service, which would otherwise be a covered benefit under a subscriber contract or governmental health benefit program, denied on appeal, in whole or in part, pursuant to title one of this article on the grounds that such health care service is not medically necessary, and

(ii) the health care plan has rendered a final adverse determination with respect to such health care service or both the plan and the enrollee have jointly agreed to waive any internal appeal; or

(b) (i) the enrollee has had coverage of a health care service denied on the basis that such service is experimental or investigational, and such denial has been upheld on appeal under title one of this article or both the plan and the enrollee have jointly agreed to waive any internal appeal, and

(ii) the enrollee's attending physician has certified that the enrollee has a life-threatening or disabling condition or disease (a) for which standard health services or procedures have been ineffective or would be medically inappropriate, or (b) for

which there does not exist a more beneficial standard health service or procedure covered by the health care plan, or (c) for which there exists a clinical trial, and

(iii) the enrollee's attending physician, who must be a licensed, board-certified or board-eligible physician qualified to practice in the area of practice appropriate to treat the enrollee's life threatening or disabling condition or disease, must have recommended either (a) a health service or procedure (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph b of subdivision five of section forty-nine hundred of this article) that, based on two documents from the available medical and scientific evidence, is likely to be more beneficial to the enrollee than any covered standard health service or procedure; or (b) a clinical trial for which the enrollee is eligible. Any physician certification provided under this section shall include a statement of the evidence relied upon by the physician in certifying his or her recommendation, and

(iv) the specific health service or procedure recommended by the attending physician would otherwise be covered under the policy except for the health care plan's determination that the health service or procedure is experimental or investigational.

3. The health care plan may charge the enrollee a fee of up to fifty dollars per external appeal; provided that, in the event the external appeal agent overturns the final adverse determination of the plan, such fee shall be refunded to the enrollee. Notwithstanding the foregoing, the health plan shall not require the enrollee to pay any such fee if the enrollee is a recipient of medical assistance or is covered by a policy pursuant to title one-A of article twenty-five of this chapter. Notwithstanding the foregoing, the health plan shall not require the enrollee to pay any such fee if such fee shall pose a hardship to the enrollee as determined by the plan.

4. An enrollee covered under the Medicare or Medicaid program may appeal the denial of a health care service pursuant to the provisions of this title, provided, however, that any determination rendered concerning such denial pursuant to existing federal and state law relating to the Medicare or Medicaid program or pursuant to federal law enacted subsequent to the effective date of this title and providing for an external appeal process for such denials shall be binding on the enrollee and the insurer and shall supersede any determinations rendered pursuant to this title.
NB Effective 99/07/01 .

***§ 4911. Powers of the commissioner.**

1. The commissioner shall have the power to grant and revoke certifications of external appeal agents to conduct external appeals requested pursuant to either paragraph (a) or

(b) of subdivision two of section forty-nine hundred ten of this title or pursuant to both such paragraphs.

2. If, after reviewing the application authorized by section forty- nine hundred twelve of this title, the commissioner is satisfied that the applicant meets the requirements of this section, the commissioner shall issue a certificate to the applicant. A certificate issued under this section shall be valid for a period of not more than two years.

3. In order to be re-certified, an external appeal agent must demonstrate to the commissioner on forms prescribed by the commissioner that it continues to meet all applicable standards required by this title. Re-certification under this section shall be valid for a period of not more than two years.
*NB Effective 99/07/01 .

***§ 4912. Standards for certification.**

1. The commissioner shall develop an application for certification. At a minimum, applicants shall provide:

(a) a description of the qualifications of the clinical peer reviewers retained to conduct external appeals of final adverse determinations, including such reviewers' current and past employment history and practice affiliations;

(b) a description of the procedures employed to ensure that clinical peer reviewers conducting external appeals are:

(i) appropriately licensed, registered or certified;

(ii) trained in the principles, procedures and standards of the external appeal agent; and

(iii) knowledgeable about the health care service which is the subject of the final adverse determination under appeal;

(c) a description of the methods of recruiting and selecting impartial clinical peer reviewers and matching such reviewers to specific cases;

(d) the number of clinical peer reviewers retained by the external appeal agent, and a description of the areas of expertise available from such reviewers and the types of cases such reviewers are qualified to review;

(e) a description of the policies and procedures employed to protect the confidentiality of individual medical and treatment records in accordance with applicable state and federal laws;

(f) a description of the quality assurance program established by the external appeal agent pursuant to paragraph (c) of subdivision two of the section;

(g) the names of all corporations and organizations owned or controlled by the external appeal agent or which owns or controls such agent, and the nature and extent of any such ownership or control;

(h) the names and biographies of all directors, officers, and executives of the external appeal agent;

(i) an experimental and investigational treatment review plan to conduct appeals pursuant to subparagraph (B) of paragraph (d) of subdivision two of section forty-nine hundred fourteen of this title; and

(j) a description of the fees to be charged by agents for external appeals.

2. The commissioner shall, at a minimum, require an external appeal agent to:

(a) appoint a medical director, who is a physician in possession of a current and valid non-restricted license to practice medicine. Such director shall be responsible for the supervision and oversight of the external appeal process;

(b) develop written policies and procedures governing all aspects of the appeal process, including, at a minimum:

(i) procedures to ensure that appeals are conducted within the time frames specified in section forty-nine hundred fourteen of this title, and any required notices are provided in a timely manner;

(ii) procedures to ensure the selection of qualified and impartial clinical peer reviewers. Such reviewers shall be qualified to render determinations relating to the health care service which is the subject of the final adverse determination under appeal;

(iii) procedures to ensure the confidentiality of medical and treatment records and review materials; and

(iv) procedures to ensure adherence to the requirements of this title by any contractor, subcontractor, subvendor, agent or employee affiliated by contract or otherwise with such external appeal agent;

(c) establish a quality assurance program. Such program shall include written descriptions, to be provided to all individuals involved in such program, of the organizational arrangements and ongoing procedures for the identification, evaluation, resolution and follow-up of potential and actual problems in external appeals performed by the external appeal agent and to ensure the maintenance of program standards pursuant to this section;

(d) establish a toll-free telephone service to receive information on a 24-hour-a-day 7-day-a-week basis relating to external appeals pursuant to this title. Such system shall be capable of accepting, recording or providing instruction to incoming telephone calls during other than normal business hours, and;

(e) develop procedures to ensure that:

(i) appropriate personnel are reasonably accessible not less than forty hours per week during normal business hours to discuss patient care and to allow response to telephone requests, and

(ii) response to accepted or recorded messages shall be made not less than one business day after the date on which the call was received.

3. No entity shall be qualified to submit such request for application if it owns or controls, is owned or controlled by, or exercises common control with, any of the following:

(a) any national, state or local illness, health benefit or public advocacy group;

(b) any national, state or local society or association of hospitals, physicians, or other providers of health care services; or

(c) any national, state or local association of health care plans.

4. A health care plan shall transmit, and an external appeal agent shall be authorized to receive and review, an enrollee's medical and treatment records in order to conduct an external appeal pursuant to this title.

5. An external appeal agent shall provide ready access to the commissioner to all data, records, and information collected and maintained concerning such agent's external appeal activities.

6. An external appeal agent shall agree to provide the commissioner such data, information, and reports as the commissioner determines necessary to evaluate the external appeal process established pursuant to this title.

7. The commissioner shall provide, upon the request of any interested person, a copy of all non-proprietary information filed with the commissioner by the external appeal agent. The commissioner may charge a reasonable fee to the interested person for reproducing the requested information.
* NB Effective 99/07/01 .

*** § 4913. Conflict of interest.**

1. No external appeal agent or officer, director, or management employee thereof; or clinical peer reviewer employed or engaged thereby to conduct any external appeal pursuant to this title, shall have any material professional affiliation, material familial affiliation, material financial affiliation, or other affiliation prescribed pursuant to regulation, with any of the following:

(a) the health care plan;

(b) any officer, director, or management employee of the health care plan;

(c) any health care provider, physician's medical group, independent practice association, or provider of pharmaceutical products or services or durable medical equipment, proposing to provide or supply the health service;

(d) the facility at which the health service would be provided;

(e) the developer or manufacturer of the principal health service which is the subject of the appeal; or

(f) the enrollee whose health care service is the subject of the appeal, or the enrollee's designee.

2. Notwithstanding the provisions of subdivision one of this section, the commissioner shall promulgate regulations to minimize any conflict of interest where such conflict may be unavoidable.
* NB Effective 99/07/01 .

***§ 4914. Procedures for external appeals of adverse determinations.**

1. The commissioner shall establish procedures by regulation to randomly assign an external appeal agent to conduct an external appeal, provided that the commissioner may establish a maximum fee which may be charged for any such external appeal, or the commissioner may exclude from such random assignment any external appeal agent which charges a fee which she deems to be unreasonable.

2. (a) The enrollee shall have forty-five days to initiate an external appeal after the enrollee receives notice from the health care plan, or such plan's utilization review agent if applicable, of a final adverse determination or denial or after both the plan and the enrollee have jointly agreed to waive any internal appeal. Such request shall be in writing in accordance with the instructions and in such form prescribed by subdivision five of this section. The enrollee, and the enrollee's health care provider where applicable, shall have the opportunity to submit additional documentation with respect to such appeal to the external appeal agent within such forty-five-day period; provided however that when such documentation represents a material change from the documentation upon which the utilization review agent based its adverse determination or upon which the health plan based its denial, the health plan shall have three business days to consider such documentation and amend or confirm such adverse determination.

(b) The external appeal agent shall make a determination with respect to the appeal within thirty days of the receipt of the enrollee's request therefor, submitted in accordance with the commissioner's instructions. The external appeal agent shall have the opportunity to request additional information from the enrollee, the enrollee's health care provider and the enrollee's health care plan within such thirty-day period, in which case the agent shall have up to five additional business days if necessary to make such determination. The external appeal agent shall notify the enrollee and the health care plan, in writing, of the appeal determination within two business days of the rendering of such determination.

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this subdivision, if the enrollee's attending physician states that a delay in providing the health care service would pose an imminent or serious threat to the health of the enrollee, the external appeal shall be completed within three days of the request therefor and the external appeal agent shall make every reasonable attempt to immediately notify the enrollee and the health plan of its determination by telephone or facsimile, followed immediately by written notification of such determination.

(d) (A) For external appeals requested pursuant to paragraph (a) of subdivision two of section forty-nine hundred ten of this title, the external appeal agent shall review the utilization review agent's final adverse determination and, in accordance with the provisions of this title, shall make a determination as to whether the health care plan acted reasonably and with sound medical judgment and in the best interest of the patient. When the external appeal agent makes its determination, it shall consider the clinical standards of the plan, the information provided concerning the patient, the attending physician's recommendation, and applicable generally accepted practice guidelines developed by the federal government, national or professional medical societies, boards and associations. Provided that such determination shall:

(i) be conducted only by one or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a notice of appeal determination which shall include the reasons for the determination; provided, however, that where the final adverse determination is upheld on appeal, the notice shall include the clinical rationale, if any, for such determination,

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the enrollee, and

(v) be admissible in any court proceeding.

(B) For external appeals requested pursuant to paragraph (b) of subdivision two of section forty-nine hundred ten of this title, the external appeal agent shall review the proposed health service or procedure for which coverage has been denied and, in accordance with the provisions of this title and the external agent's experimental and investigational treatment review plan, make a determination as to whether the patient costs of such health service or procedure shall be covered by the health care plan; provided that such determination shall:

(i) be conducted by a panel of three or a greater odd number of clinical peer reviewers,

(ii) be accompanied by a written statement:

(1) that the patient costs of the proposed health service or procedure shall be covered by the health care plan either: when a majority of the panel of reviewers determines, upon review of the applicable medical and scientific evidence (or upon confirmation that the recommended treatment is a clinical trial), the enrollee's medical record, and any other pertinent information, that the proposed health service or treatment (including a pharmaceutical product within the meaning of subparagraph (B) of paragraph (b) of subdivision five of section forty-nine hundred of this article) is likely to be more beneficial than any standard treatment or treatments for the enrollee's life-threatening or disabling condition or disease (or, in the case of a clinical trial, is likely to benefit the enrollee in the treatment of the enrollee's condition or disease); or when a reviewing panel is evenly divided as to a determination concerning coverage of the health service or procedure, or

(2) upholding the health plan's denial of coverage,

(iii) be subject to the terms and conditions generally applicable to benefits under the evidence of coverage under the health care plan,

(iv) be binding on the plan and the enrollee, and

(v) be admissible in any court proceeding.

As used in this subparagraph (B) with respect to a clinical trial, patient costs shall include all costs of health services required to provide treatment to the enrollee according to the design of the trial. Such costs shall not include the costs of any investigational drugs or devices themselves, the cost of any nonhealth services that might be required for the enrollee to receive the treatment, the costs of managing the research, or costs which would not be covered under the policy for noninvestigational treatments.

3. No external appeal agent or clinical peer reviewer conducting an external appeal shall be liable in damages to any person for any opinions rendered by such external appeal agent or clinical peer reviewer upon completion of an external appeal conducted pursuant to this section, unless such opinion was rendered in bad faith or involved gross negligence.

4. Payment for an external appeal shall be the responsibility of the health care plan. The health care plan shall make payment to the external appeal agent within forty-five days from the date the appeal determination is received by the health care plan, and the health care plan shall be obligated to pay such amount together with interest there- on calculated at a rate which is the greater of the rate set by the commissioner of taxation and finance for corporate taxes pursuant to paragraph one of subsection (e) of section one thousand ninety-six of the tax law or twelve percent per annum, to be computed from the date the bill was required to be paid, in the event that payment is not made within such forty-five days.

5. The commissioner, in consultation with the superintendent of insurance, shall promulgate by regulation a standard description of the external appeal process established under this section, which shall provide a standard form and instructions for the initiation of an external appeal by an enrollee.
* NB Effective 99/07/01

***§ 4915. Prohibited practices.**

An external appeal agent shall not, with respect to external appeal activities, permit or provide compensation or anything of value to its employees, agents, or contractors based on:

1. either a percentage of the amount by which a claim is reduced for payment or the number of claims or the cost of services for which the person has denied authorization or payment; or

2. any other method that encourages the upholding of an adverse determination.
* NB Effective 99/07/01

*§ 4916. Oversight and surveillance of the external appeal process.

1. The commissioner shall have the power to:

(a) review the activities of the health care plans and external appeal agents pursuant to this title, including the extent to which such plans and agents adhere to the standards and time frames required pursuant to this title;

(b) investigate complaints by enrollees regarding requests for and processing of external appeals; and

(c) conduct random audits of health care plans and external appeal agents to determine compliance with the provisions of this title.

2. Each health care plan and external appeal agent shall annually, in such form as the commissioner shall require, report the number of external appeals requested by enrollees and the outcomes of any such external appeals.

3. The commissioner shall annually report, by plan and agent, such information to the governor and the legislature, provided that no such information shall be included which would otherwise be deemed confidential information within the meaning of this chapter.
* NB Effective 99/07/01